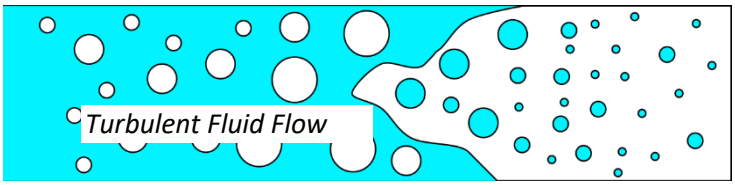
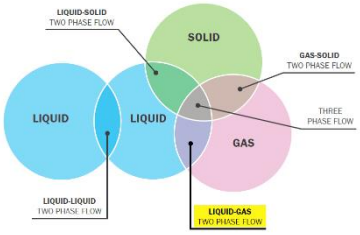
The TFF Report

Endoscopes have been linked to many infectious outbreaks; the need for a reliable sampling method is paramount to ensure endoscopes are being reprocessed effectively. In order to meet this need, Healthmark Industries Co. partnered with Dr. Labib of Novalflux to create a method in order to harness a science called turbulent fluid flow (TFF) and utilize it in the reprocessing of endoscopes. TFF occurs when fluid (in this case, water) mixes and fluctuates with air (see picture to the right).



Currently, there is nothing like TFF in the Sterile Processing market. There are two common extraction methods of endoscopes which are used, including the flush and flush brush flush (FBF). As the FBF creates friction in an endoscope to better extract material, the TFF also creates friction, but does not require an insert of any foreign body into the endoscope.



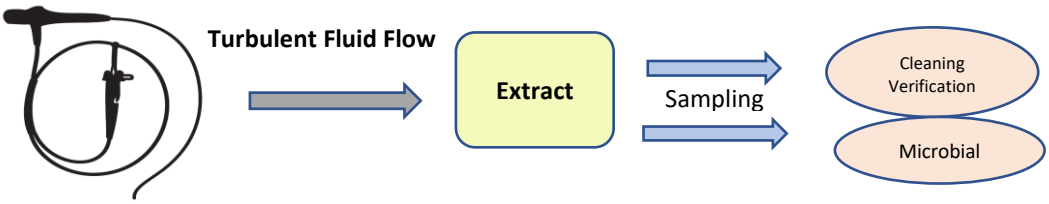
Additionally, there are some endoscope channels (air-water channels, auxiliary water channels and some ureteroscopes channels) that are too small to have a brush inserted, but the TFF pushes air and water, creating friction, through these channels, without inflicting any damage in the endoscope. The flush method can also push water through these channels, but does not create any friction, resulting in less material collection to sample from. By extracting a higher percentage of the material (bioburden) in the endoscope, including proteins and carbohydrates, a higher accuracy in sampling is possible, ensuring a truer result of the effectiveness of reprocessing.

In order to utilize the science of the TFF, Healthmark had to come up with entirely new concepts and configurations, working with and testing the TFF daily. The entire product Healthmark has been working on, and will soon release, is named after the science involved: the TFF. Healthmark has partnered with the FDA, universities and hospitals. There have been over 3,000 hours spent working on the TFF (not including outside efforts by those Healthmark has recruited). They've partnered with

experts and engineers in sterile processing, bottle-cap design and electrical manifolds. This report will detail sections of the TFF that Healthmark has created and progressed through and detail the continuance of this work, all in order to release this new and exciting product into the realm of endoscope extraction and sampling.

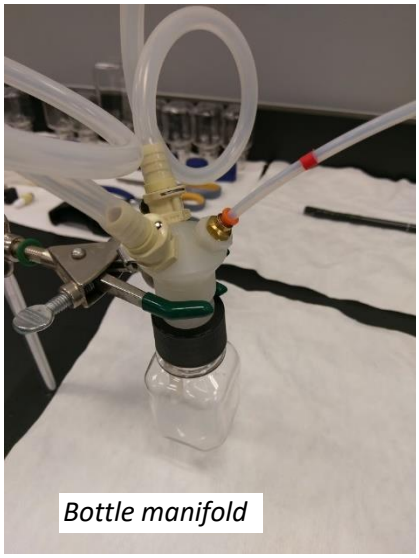
Specifics of TFF with Endoscopes

In order to create a turbulent fluid flow appropriate and most ideal for endoscopes (these diameters were discovered through much testing), 20 mL is mixed with hospital-grade air and pushed through the endoscope. The ideal flow rate is around 17 or 18 mL per minute, and the process takes one minute and 45 seconds. The water collected in the bottle is then used with Procheck-W semiquantitative protein test. The sterile version of the TFF will be able to test for microbial and organic residuals.



In addition to extraction, the TFF (product) will have an added benefit of a drying feature, in which air will be pushed through the endoscope for ten minutes at 25 psi. While there is nothing like the TFF on the market, there currently isn't a similar drying mechanism on the market either (there are wall mounts for drying and drying cabinets).

Collection Bottle and Cap



Bottle manifold

When TFF testing first began, a bottle manifold was used, in addition to tubing and a clamp, to hold the distal tip of the endoscope and collect the TFF extraction material. And as there are a variety of endoscopes in differing sizes, the bottle manifold had the ability to secure distal tips of varying sizes, depending on the tubing which was paired with the bottle manifold. It was desirable that the cap would be cost efficient enough to be single-use, so that it would not have to be sterilized between uses. This bottle manifold was too expensive to be a feasible single-use cap. On top of the concerning expense of the manifold, the distal tip being pushed into tubing, which would then hook to the bottle manifold, presented the potential of damage to the endoscope (which is an expensive instrument).

Eventually, a two-port VersaCap was used as the collection cap for the TFF. While these caps were substantially cheaper than the bottle manifold, they were still too costly to be single-use and presented the same danger to the distal tip. After much market research, a cost-effective cap, that could create an airtight seal without leaving room for potential damage of the distal tip, could not be found. In order to have a cost-effective cap, Healthmark partnered with Caplugs to create a custom cap for the TFF. These caps would fit a bottle that could be bought off the shelf and would need to be used with the various sizes of endoscopes. After some brainstorming, a barbed-style cap was designed and tested with the TFF. Though the cap was versatile enough to work with the various sizes of endoscopes, it still presented a danger to the distal tip when pulling the tip out of the tubing. The barbed style also held water (on the smaller barbs) when the bigger sized barb was being used for the larger sized endoscope (see picture to the right).

Barbed-style Cap

After some additional brainstorming and collaboration with sterile processing engineers, a design mirroring what is often used for electrical purposes was conceptualized to be the new cap for the TFF. A compression-styled fitting would be used to hold an endoscope in the TFF cap. This concept is based around a soft material, in this case silicone rubber, which would be used to hold a scope's distal tip and create an air-tight seal. It would consist of three parts: the bottom threads for securing the cap, a rubber insert (of variable size), and an open-top screw cap that is tightened in order to reduce the diameter of the rubber opening and to create a firm compression seal around the distal tip. Caplugs was able to create this cap cost efficiently, and after testing, the cap was found to be suitable for the TFF.

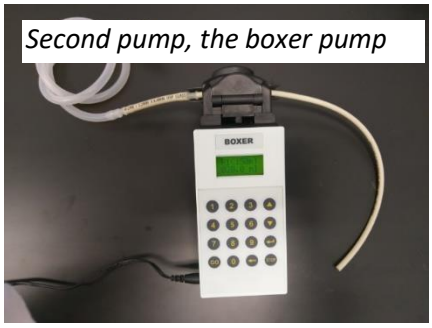
Compression-styled cap design

Compression-styled cap

Water and Air Sources

When Healthmark first began testing with the TFF, laboratory technicians were using a metering pump form Fluid Metering, INC. This pump was ineffective; it was extremely expensive ($975.00 each) and the user had to calculate the flowrate for each use. Furthermore, the user had to count down and manually stop the flow on her own. This sort of system would not be functional in a sterile processing department.

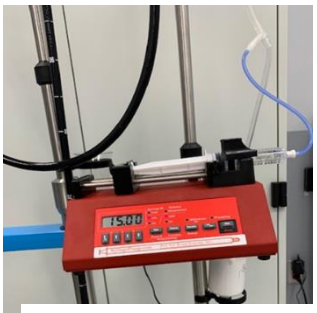
Fluid Metering Inc Stroke rate controller



Second pump, the boxer pump

As an alternative to the aforementioned metering pump, a boxer pump began to be used. The boxer pump was a better option in comparison to the metering pump, but the manufacturer could not meet production needs and would be on backorder for an additional one year to two years on the product. This wouldn't suffice for the TFF, and alternative options had to be explored.

Healthmark decided to use a syringe pump to push the water through the TFF. This was more cost effective than the previous mentioned pumps, and it was also easier to mount onto the EndoDolly™. Once the syringe pump had been programmed to push at a certain rate, it remained programmed at that rate. It also made sterile-water easy-to-access, as prefilled sterile water syringes are common on the market. Prior to using the syringe pump, Healthmark was looking at prefilled bottles of sterile water, which were more expensive and harder to set-up on the TFF and EndoDolly™.



Syringe pump on EndoDolly™

In order to push the air through correctly, an air-pressure gage intercepts the hospital air and regulates it down to 27 psi. This is done as to not damage the inside of the endoscope. Once the water would run its course, the air would need to run for thirty more seconds, after which the air source would need to be cut off by the air valve.

While this system does the job well for the TFF, it isn't exactly user friendly. A new air/water-pump system would need to be created custom, so that it was easy to understand and execute the TFF in the sterile processing realm.

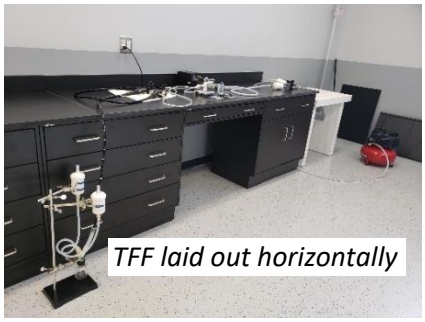
Healthmark Industries contacted a variety of engineers to find a company that had the capability to create such a system. Healthmark Industries eventually ended up choosing Posthaste Design and Engineering to create a product capable of performing the duties of the TFF. This design will have to have the following specifications in order to perform effectively and meet the standards for the TFF and Drying: a custom housing suitable for lab environment, a syringe pump for a 20 mL syringe, a pump which must not back drive at or below 27 psi air, a regulator and manifold (in order to maintain appropriate water pressure and air pressure for designated times), two solenoid valves, a graphic overlay with Healthmark Industries branding, a LED display for a countdown timer, a system contained in sheet metal enclosure with clamp for 1" IV pole, four user interface buttons (including reset syringe pump, start extraction cycle, start drying cycle, and stop all).

Posthaste Design and Engineering completed the first prototype the TFF control box, which included the aforementioned specifications. Testing is currently being undertaken to observe how the prototype performs in action. After testing of the prototype is completed, any additional adjustments will be made, and a revised control box will be created to ensure apt performance. This future system will provide the ease-of-use needed to be effective in the market of sterile processing, while also being able to perform the tasks of TFF. See a picture of the TFF control box (prototype) below.

TFF Control Box (first version/prototype)

The EndoDolly™

Sterile Processing Departments are often limited on space. There isn't much leeway to add new products in a sterile processing department. At the beginning of TFF testing, the TFF process was laid out horizontally over the counter. This sort of set-up would not be feasible in a sterile processing department. In order to work with the limited space future users will have, the TFF was placed onto the EndoDolly™, a system designed to hang scopes on three self-adjusting extension poles and transport endoscopes as necessary. This system is on top of five-wheels and allows for ease-of-mobility. The EndoDolly™ is a custom Healthmark product, as is the TFF, and combining the two units was an ideal match. Gravity is on the side of the TFF with the



TFF laid out horizontally

EndoDolly™

EndoDolly™, as the water goes down into the collection bottle, and in addition to this benefit, the system also works well for drying, which will be a further feature of the TFF once it's ready for market.

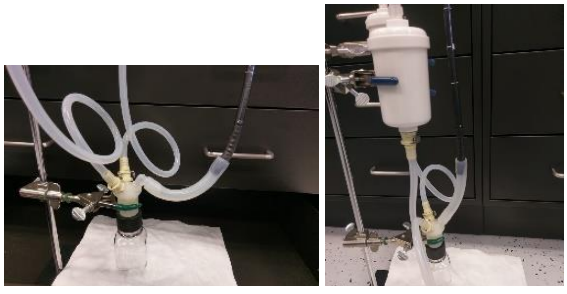
Testing

Though the TFF has yet to be market ready and released, Healthmark has made and continues to make great progress. All of this progress can be attributed to the people working with the TFF, from concept to cultivation. This is especially true of those working hands-on with the TFF in the lab. Throughout this report, the materials and mechanisms that comprise the TFF have been discussed. In order to determine those materials and mechanisms, the Research and Development (R&D) team had to do various types of testing. Since the TFF entered Healthmark R&D in September of 2018, Healthmark personnel spent thousands of hours working with the TFF and the biggest portion of those hours were spent in the R&D lab.

When TFF testing first began, 10 mL of water was used to push through the endoscope, creating a turbulent fluent flow when mixed with air. While the lab was testing and comparing water pumps and connections, it was found that having a longer run time, which provides more exposure time to TFF, equated to a higher extraction material collected. In order to have a longer run time, 20 mL extractions needed to be performed, doubling the run time and the water measurement of 10 mL. See comparative results below between 10 mL and 20 mL extractions.

Average Volume Recovered for Each Connector & Air: Regardless of Pump			
10 mL Results		20 mL Results	
Elbow Connector - PP	79.8%	Elbow Connector - PP	89.10%
Straight Connector - PP	88.1%	Straight Connector - PP	94.00%
Straight Connector - nPP	86.2%	Straight Connector - nPP	94.8%

Furthermore, as can be noted in the table above, various connections were tested in order to find the option that lead to the highest percentage of volume collected/protein extracted. The elbow connector demonstrated less volume recovery in comparison to the straight connector.



Elbow connector (left) and the straight connector (right).

The TFF has still been tested within various university hospitals in partnership with Healthmark and the FDA. As of yet, Healthmark has introduced the TFF to the University of Michigan, the University of Minnesota, and Clemson University. Healthmark personnel attended each of these universities, demonstrating and assisting with TFF set-up. Once university personnel were familiar and comfortable with the TFF, they did continuous testing in order to see the results of TFF extractions. The University of Michigan performed 20 tests total with TFF, all of which were with colonoscopes. Washington Adventist Healthcare performed 33 tests total with TFF with gastroscopes and colonoscopes. The University of Minnesota performed ten tests with colonoscopes and gastroscopes.

While the TFF has shown to extract more than flush extractions, it has also been shown to access various areas in the endoscopes the flush brush flush extraction method cannot access. Testing is still being pursued, and there will specific accuracies showing the benefits and results of TFF extraction soon.

Outside testing has also demonstrated that turbulent fluent flow is more effective than flush blush flush and flush extraction methods. According to an article titled "Turbulent fluid flow is a novel closed-system sample extraction method for flexible endoscope channels of various inner diameters," published in the *Journal of Microbiological Methods* (Soyn, et al. 21), that tested turbulent fluid flow in comparison to flush and flush brush flush extraction methods, "This study demonstrated that TFF can provide optimal sample extraction for patient-used colonoscopes for cleaning verification testing as well as for culture testing after HLD (High Level Disinfection; with or without storage)." See testing results (figure T) of TFF to the right. Additionally, the article highlighted (Soyn, et al. 34), "extraction of bacteria from biofilm was better by TFF compared to Flush

Parameter	Suction Biopsy channel	Air/Water channel	Auxiliary channel
With TFF	% Efficiency extraction based on CFU/cm^2		
E. faecalis Average	98.44	99.09	99.96
P. aeruginosa Average	98.66	99.21	99.98
C. albicans Average	99.39	99.60	99.97
Flush brush flush or flush alone (no TFF)	% Efficiency extraction based on CFU/cm^2		
E. faecalis Average	83.68	89.95	95.76
P. aeruginosa Average	85.38	89.03	85.39
C. albicans Average	86.68	88.73	97.54

Fig. T. TFF efficiency extraction results from "Turbulent fluid flow is a novel closed-system sample extraction method for flexible endoscope channels of various inner diameters." Journal of Microbiological Methods

extraction," "TFF extraction of organic markers from biofilm was superior to flush extraction," "TFF extraction efficacy from inoculated colonoscope channels was >98%," and "TFF extraction was significantly better than F or FBF for SB and AUX channels."

In the Works

The final unit, that has the capabilities to run the TFF (pushing water and air through at appropriate speeds for the designated amount of time) and run a drying system, will soon be finished. Once this is finished (and the final caps have been made) and designed in a user-friendly manner, a price-point and marketing plan for the TFF will be created. Healthmark Industries is very excited to release this much-needed product onto the market, allowing for a thorough extraction of and leading to an accurate and reliable sampling of endoscopes. Once this sampling method is in use, the efficacy of endoscope reprocessing will be able to be accurately measured, preventing the potential for dangerous infectious outbreaks and hospital associated infections.

References

Sohn, S. Y., Alfa, M. J., Lai, R., Tabani, Y., & Labib, M. E. (2020). Turbulent fluid flow is a novel closed-system sample extraction method for flexible endoscope channels of various inner diameters. Journal of Microbiological Methods, 168, 105782. https://doi.org/10.1016/j.mimet.2019.105782